# Exhibit A

#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY	) MDL NO. 1456
AVERAGE WHOLESALE PRICE LITIGATION	) CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	) Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.,	) Magistrate Judge Marianne B. Bowler
No. 06-CV-11337-PBS	)

# ABBOTT LABORATORIES, INC.'S REPLY IN SUPPORT OF ITS MOTION TO COMPEL TESTIMONY OF GOVERNMENT WITNESSES

Rather than address the importance of the testimony that Abbott claims it was improperly denied or seriously grapple with the relevance of such testimony to the Government claims and Abbott's defenses, the Government dedicates most of its response brief to the flawed assertion that Abbott is simply rearguing issues already decided by the Court. Tellingly, the Government does not (and, in fact, cannot) point to any decision from either the Magistrate or District Court Judge that resolves or even addresses whether the particular testimony Abbott seeks in its motion can be shielded by the deliberative process privilege. That is because the Court's rulings on the deliberative process privilege have focused exclusively on documentary evidence and have not addressed the privilege's applicability to specific deposition questioning.

As countless other courts have done in the context of privilege disputes, this Court has declined to rule on whether certain passages of deposition testimony are privileged in the abstract or with broad brush strokes. Instead, the Court has left the issue of whether, and to what extent, the deliberative process privilege applies to testimony undecided up to this point, presumably recognizing that such decisions can oftentimes best be made after the depositions have taken place, the privilege has been asserted, and a proper record has been created and presented to the Court for decision on a question-by-question basis. *See infra*, at pgs. 4-5.

The Government's attempt to avoid scrutiny of its instructions not to answer specific questions based upon past rulings of the Court should be rejected out of hand. When the deposition passages at issue in this motion are considered in full by the Court, it will be clear that the Government is suppressing evidence that is highly relevant to the Government's claims and Abbott's defenses, if not indispensable considering the lapse of time and the Government's failure to preserve documents. The Government's use of the deliberative process privilege to conceal evidence damaging to its claims, and thus gain an upper hand in this civil litigation, not only demeans the purpose of the privilege, but also contradicts the rules of discovery which allow the accused to fully discover and defend against the accusations lodged against it.

#### I. THE ISSUES IN ABBOTT'S INSTANT MOTION HAVE NEVER BEEN ADDRESSED OR RESOLVED BY THE COURT.

The Court has yet to rule on the applicability or scope of the deliberative process privilege with respect to deposition testimony, let alone pass on the specific deposition passages at issue in Abbott's instant motion. Instead, the Court's rulings have addressed only the privilege's impact on the production of documents while remaining silent on the privilege's impact on lines of questioning in fact witness depositions.

For instance, in Magistrate Judge Bowler's very first decision addressing the deliberative process privilege—the decision that set in motion objections by both parties, additional briefing by both parties, and subsequent rulings by both the District Court and Magistrate Judge—she stated the following:

ORDER entered denying 3959 Motion to Compel, at this time without prejudice except to the extent that the approximately 60 documents that expressly reference Abbott Laboratories, Inc. ("Abbott") and/or the subject drugs as well as those documents that concern the government's knowledge of the common use of spreads with respect to published AWPs shall be produced. The declarations of Robert A. Vito and Leslie V. Norwalk convince this court that the documents are both predecisional and deliberative .... Having weighed all of "the competing interests," ... Abbott's need for the foregoing documents is substantial particularly

in light of their relevance and the showing that memories have faded with the passage of time. Abbott shall, as stated, "keep [the *documents*] strictly confidential."

8/13/2007 Order (Ex. 1) (emphasis added). It is clear from the language of this ruling that the Court was focused exclusively on the privilege's applicability to documents and did not address whether the privilege applied to specific lines of deposition questioning. The Government's suggestion otherwise is dubious at best.<sup>1</sup>

Like the initial deliberative process privilege ruling, all of the Court's subsequent rulings on the deliberative process privilege addressed only the Government's obligations in producing documents, leaving the issue of deposition testimony for another day. *See* 11/9/2007 Order (Ex. 2) (addressing only documents); 2/1/2008 Order (Ex. 3) (addressing only documents); 3/14/2008 Order (Ex. 4) (addressing only documents). It is readily apparent from the record that, contrary to the Government's short-cut attempt to dispose of the instant motion, Abbott is not rearguing any matters that have been decided—either implicitly or explicitly—by either the Magistrate or District Court Judge.<sup>2</sup>

## II. PRIVILEGE ISSUES ARISING IN DEPOSITIONS ARE PROPERLY ADDRESSED ON A QUESTION-BY-QUESTION BASIS.

The Court's decision to defer consideration of the propriety of the Government's privilege objections during depositions is consistent with the well-established principle that privilege issues should be decided on a question-by-question basis once the deposition has taken place, the privilege has been asserted, and a proper record has been created and presented to the

<sup>&</sup>lt;sup>1</sup> Moreover, the Government's suggestion that this ruling, and the other deliberative process privilege rulings that spawned from this initial ruling, put to rest the dispute regarding the scope of the privilege in the context of deposition testimony is disingenuous. If anything, the Court recognized that certain deliberative process questions—likely those that were not addressed in its explicit ruling regarding documents (*i.e.*, deposition testimony)—may need to resolved at a future time, and accordingly qualified the ruling as being made "without prejudice." *See id.* Government counsel cannot completely insulate its suppression of relevant testimony by relying on such a thin reed.

<sup>&</sup>lt;sup>2</sup> Similarly, objections by the Government to specific lines of questioning were not addressed during either of the two oral arguments before Magistrate Judge Bowler.

Court for review. *See United States v. Lawless*, 709 F.2d 485, 487 (7th Cir. 1983) ("The claim of privilege must be made and sustained on a question-by-question or document-by-document basis: a blanket claim of privilege is unacceptable.") (citation omitted); *In re Air Crash at Taipei, Taiwan on Oct. 31, 2000*, 211 F.R.D. 374, 376 n.2 (C.D. Cal. 2002) (same); *see also Evans v. City of Chicago*, 231 F.R.D. 302, 320 (N.D. Ill. 2005) ("the proponent of the privilege must establish the privilege on a document-by-document (or question-by-question) basis"). This practice is equally followed when the privilege asserted is the deliberative process privilege. *See United States v. Motorola*, No. Civ.A. 94-2331TFH/JMF, 1999 WL 552558, \*2 (D.D.C. May 27, 1999) (finding that the court was "obliged to rule on the application of [the deliberative process privilege] on a question by question basis").

The Government's faulty reliance on the Court's general pronouncements regarding the discoverability of *documents* is contrary to this law and the Court's past practice of examining privilege assertions in the context of depositions. *See* 12/18/2006 Hr'g Tr. at 136 (Judge P. Saris) (Ex. 5) (rejecting the plaintiffs' request for "broad rulings" that the witness's testimony was not privileged, and instead indicating that a "question-by-question" analysis might be better: "If there's another more discrete record and discrete questions ..., I think, that could be asked and these are doors that probably could be opened, *but it will be one by one, step by step.*"); *see also* 11/13/2006 Hr'g Tr. at 6-7, 14-15 (Judge P. Saris) (Ex. 6) (indicating the Court's preference of reviewing the deposition transcript to make determinations regarding the scope of the deliberative process privilege). This Court has yet to decide whether the Government's suppression of testimony in the specific questioning put at issue by Abbott's motion were proper. Its past rulings in no way bar consideration of this important issue now.

### III. THE SUPPRESSED TESTIMONY THAT ABBOTT SEEKS IS HIGHLY RELEVANT.

Each point that the Government makes in support of its argument that the suppressed testimony Abbott seeks is irrelevant is illogical and flawed. First, the Government trumpets the fact that, contrary to Abbott's assertions, it did do something to change its AWP-based payment methodology by passing the Medicare Modernization Act of 2003 ("MMA")—a change that occurred well after the relevant claims period in this case. This entirely misunderstands Abbott's contention and the discovery sought by Abbott.

The Government's citation to the MMA is indeed curious, as it explains why much of the testimony sought by Abbott is critically relevant to this case. In addition to reducing drug ingredient payments, the MMA drastically increased the fees paid to physicians to administer those drugs—particularly for the drugs at issue in this case. *See* Abbott's Opening Br. at pg. 10, n.4. Prior to MMA, Abbott contends, not without support, that Medicare was deliberately cross-subsidizing insufficient administration and dispensing fees with a margin on the drug ingredient payment. *See id.* at pgs. 10-13. Much of the questioning at issue in this motion goes to that subject. For example, Robert Vito testified to specific discussions that he had with CMS about the fact that home infusion and respiratory drug providers were using the drug margin to pay for the services necessary to administer those therapies. *See id.* at 4-5. Those discussions may have included a specific acknowledgement by CMS not to increase service or dispensing fees *because* of the spread in drug ingredient costs. Such evidence is irrefutably relevant to this case, but has been blocked by the Government's objections.

Second, the Government argues that its decision to maintain an AWP-based payment system, regardless of its knowledge concerning AWPs or its intentional policy choices to pay a margin to providers for drugs they administered, cannot defeat the Government's fraud claim.

Overwhelming authority tells us that this is simply not the case—evidence regarding Government officials' knowledge of how published AWPs stacked up to actual acquisition costs and their knowing acquiescence in or approval of a payment system based on published AWPs is relevant to nearly every element of the Government's common law fraud claim (*e.g.*, reliance, causation, damages).

With respect to the reliance element of its fraud claim, evidence of Government knowledge and action (or, more accurately, inaction) must be examined to determine if the professed reliance actually occurred and whether it was reasonable. See, e.g., Teamsters Local 282 Pension Trust Fund v. Angelos, 839 F.2d 366, 370 (7th Cir. 1988) ("In determining whether reliance was reasonable, all of the facts which plaintiff had actual knowledge of, as well as all of those it might have learned if it had used ordinary prudence, must be taken into account; if ample opportunity existed to discover the truth, then reliance is not justified.") (citation omitted); see also Amaco Enterprises Inc. v. Smolen, 61 F.3d 909 (9th Cir. 1995) ("Justifiable reliance requires a showing that plaintiff's reliance was reasonable in light of all the circumstances giving consideration to the plaintiff's intelligence and experience."). Ultimately, the Government has not (and cannot) refute that the reliance element of their fraud claim focuses on the plaintiff's knowledge and its decision-making in light of that knowledge. See Francis v. Bankcard Am., Inc., No. 93 C 5510, 1999 WL 1289110, \*8 (N.D. Ill. Jan. 4, 1999) ("The former inquiry into fraudulent intent focused on the defendants' actions. This inquiry into justifiable reliance focuses on plaintiff's actions.") (emphasis added).

Similarly, the Government's causation and damages elements of its fraud claim require examination of the Government's knowledge, decision-making, and actions. If, as it appears actually occurred, the Government used an AWP-based payment system with knowledge that it

would result in payments exceeding providers' acquisition costs (*i.e.*, the Government's alleged "overpayment"), and nonetheless chose to use such a payment system for political or policy reasons,<sup>3</sup> it cannot now claim that such "overpayments" were caused by Abbott. *See In re Mexico Money Transfer Litig.*, 164 F. Supp. 2d 1002, 1015 (N.D. Ill. 2000) (suggesting that the plaintiff "may well be unable to prove causation" because the plaintiff may have paid the defendant's rate "for reasons of speed, reliability, security, or convenience, even though they were aware that [d]efendants charged more than some competitors"); *see also JP Morgan Chase Bank v. Winnick*, 350 F. Supp. 2d 393, 405 (S.D.N.Y. 2004) ("[W]here a plaintiff actually knew at the time a representation was made that it was false, she cannot claim to have relied on the truth of that representation, and any injury she suffers is therefore not attributable to the defendant."); *Grubb v. F.D.I.C.*, 868 F.2d 1151, 1165 (10th Cir. 1989) ("Under ... causation standard, plaintiffs cannot recover for losses caused by their own failure, since they became aware of the fraud, to take reasonable steps to preserve their assets and avoid further harm.").<sup>4</sup>

At the very least, the Government's common law fraud claim exposes it to deposition discovery into its knowledge, decision-making, and actions. *See Dept. of Econ. Dev. V. Arthur Anderson & Co.*, 139 F.R.D. 295, 299 (S.D.N.Y. 1991) ("By asserting the claims of fraud against AA, the British Government necessarily places at issue questions of knowledge, justifiable

<sup>&</sup>lt;sup>3</sup> Based upon publicly-available documents, it appears that Congress and CMS used such a system not because they were duped into doing so, but because, *inter alia*, they wanted to compensate for shortfalls in other payments to providers, to encourage provider participation in the Medicare and Medicaid programs, and to encourage the use of generics by providers. *See* Abbott's Opening Br. at 10-13. Leo Sullivan, a key official from Tennessee Medicaid, recently testified that Tennessee would "add on [to] the cost" of drugs to make sure that providers were being adequately compensated for costs that were not covered by the state's dispensing fees (*e.g.*, supply or equipment costs, compounding services, nursing services). *See* Sullivan Dep. Tr. at 153-54 (Ex. 8). This is an example of the type of testimony Abbott expected to obtain from the Government's witnesses had the Government not thwarted every effort Abbott made to uncover the reasons behind CMS's decision to continue using an AWP-based payment system.

<sup>&</sup>lt;sup>4</sup> Similarly, evidence of Government knowledge and acquiescence in the payment of spreads is relevant to the Governments claims brought under the FCA, which ultimately is a fraud statute. *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004) (finding that the FCA is a fraud statute).

reliance and causation ... [A]t issue is the British Government's knowledge of DeLorean's activities, the extent of the knowledge, whether they justifiably relied upon AA's reports or whether, as the defendants contend, the government chose to ignore certain information it had before it and nonetheless approve the grants for political issues.").

Third, the Government espouses an illogical view that this Court's decision on the legal meaning of the term "average wholesale price" somehow renders all evidence of Government knowledge and decision-making irrelevant, leaving only Abbott's conduct and knowledge susceptible to discovery in this case. How the Government extrapolates this far-reaching (and self-serving) restriction on the scope of discovery from the Court's ruling on the legal definition of the term AWP is unclear. What is clear is that the Government's tortured understanding of that ruling ignores the case law cited above and disregards this Court's unequivocal statements regarding the proper scope of discovery and the relevance of Government knowledge and decision-making. See 10/11/2007 Mem. in Support of Abbott's Motion to Compel Discovery Responses to Its Documents Requests Nos. 37 and 38 (attached as Ex. 7) (setting forth the numerous comments of the Court on the relevance of evidence showing that the Government knew AWP did not reflect acquisition costs, including its comment that Government knowledge is "quite relevant" and at the "heartland" of this case); see also 2/21/2008 Order in United States v. Boehringer Ingelheim Corp., Case No. 1:07-cv-10248 (recent decision by the Court denying the Government's motion to strike certain plaintiffs' Government knowledge defenses, ruling that such issues would be addressed at summary judgment after discovery concludes).

Surely, the Government cannot seriously contend that if Abbott proves that the Government was aware of and acquiesced in the type of spreads at issue here that it can continue to claim that it was the victim of fraud. In briefing to this Court, Abbott has set forth extensive

evidence demonstrating that the state and federal governments deliberately allowed the payment of some amount of a "spread" or margin on drug payments for various reasons. *See*, *e.g.*, Abbott's Opening Br. at 10-13. Instead of explaining how this specific evidence is irrelevant, the Government completely ignores it in the hope that the Court will overlook it. Abbott does not believe that the Government can continue to argue in good faith that evidence of Government knowledge and decision-making is "irrelevant" to this fraud case.

Finally, despite Abbott's invitation, the Government's response brief articulates no harm that would result from such discovery. In fact, the Government's brief is glaringly devoid of any analysis of the balancing test that the Court employs to determine the applicability of the deliberative process privilege.

#### **CONCLUSION**

For the reasons set forth above, and for the reasons stated in Abbott's Memorandum in Support of Its Motion to Compel Testimony of Government Witnesses [Dkt. No. 5112], Abbott respectfully requests the Court overrule the assertions of the deliberative process privilege lodged by Government counsel and order the witnesses to answer the questions identified in Exhibit 1 of Abbott's opening brief.

Dated: March 21, 2007

Respectfully submitted,

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